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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,045	10/08/2003	Yih-Ming Hsiao	T-1264	8142
802	7590	06/01/2004	EXAMINER	
DELLETT AND WALTERS P. O. BOX 2786 PORTLAND, OR 97208-2786			HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER.
			1614	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/682,045

Applicant(s)

HSIAO ET AL.

Examiner

Raymond J Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/08/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**CLAIMS 1-12 ARE PRESENTED FOR EXAMINATION**

Applicants' Information Disclosure Statement filed December 8, 2003 has been received and entered into the application. As reflected by the attached, completed copy of form PTO-A820 (1 page), the cited reference has been considered.

***Claim Objections***

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 3 merely recites the intended function of the composition of claim 1 and does not provide for any further physical or otherwise material limitation.

Applicants are required to cancel the claim, amend the claim to place it in proper dependent form, or rewrite the claim in independent form.

Claims 5-9 are objected to because of the following informalities: \*\*\*

Claims 5-9 contain numerous grammatical errors and should be revised carefully. As an example of such errors, in claim 5, line 1, "comprising" should read ---comprises---; also at line 1, after "drying", ---said--- should be inserted; and at line 2, the term "obtained" should be deleted. Appropriate correction is required.

***Claim Rejection - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 4, the metes and bounds of the expression "pharmaceutical-grade ferric citrate" is unclear. In particular, such an expression fails to make clear what difference, if any, there is between applicants' ferric citrate and that ferric citrate normally employed in pharmaceutical preparations.

It is suggested that, in order to overcome this point of rejection, applicants amend claims 1 and 4 by specifying that the pharmaceutical-grade ferric citrate is of the formula as set forth in present claim 11.

***Claim Rejection - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsu (U.S. Patent No. 5,753,706, cited by Applicants) who teach pharmaceutical compositions comprising ferric citrate and a pharmaceutically acceptable carrier (col. 2, lines 49 and 55-65 and col. 3, lines 40-45).

Insofar the compositions are taught for pharmaceutical purposes, the Examiner interprets the ferric citrate of Hsu to be of a pharmaceutical-grade as required by present claim 1.

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***Claim Rejection - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu (U.S. Patent No. 5,753,706, cited by Applicants), as above, in light of Applicants' acknowledgments at page 1, line 21 – page 2, line 3 of the present specification.

Hsu further teaches the incorporation of the ferric citrate into a food composition (col. 3, line 62)

The difference between the above and the claimed subject matter lies in that Hsu fails to highlight a hydrated ferric citrate having 3.5 parts of water (present claim 11).

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However, the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because as acknowledged by applicants at pages 1-2 of the present specification:

“Although ferric citrate is commercially available, the purchased ferric citrate is a combination of iron and citric acid of indefinite composition (The Merck Index, 12th Edition, page 4068) probably because of the difficulty encountered in its preparation. People knowledgeable in the art understand and necessarily accept that commercially available ferric citrate contains different molar ratios of iron and citric acid and *also contains different amounts of hydrate.*”(emphasis added).

Thus, the skilled artisan would have expected the ferric citrate of Hsu to contain molecules of differing hydration and nothing unobvious is seen in applicants' identification of a ferric citrate having 3.5 parts of water.


Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J Henley III  
Primary Examiner  
Art Unit 1614

May 26, 2004